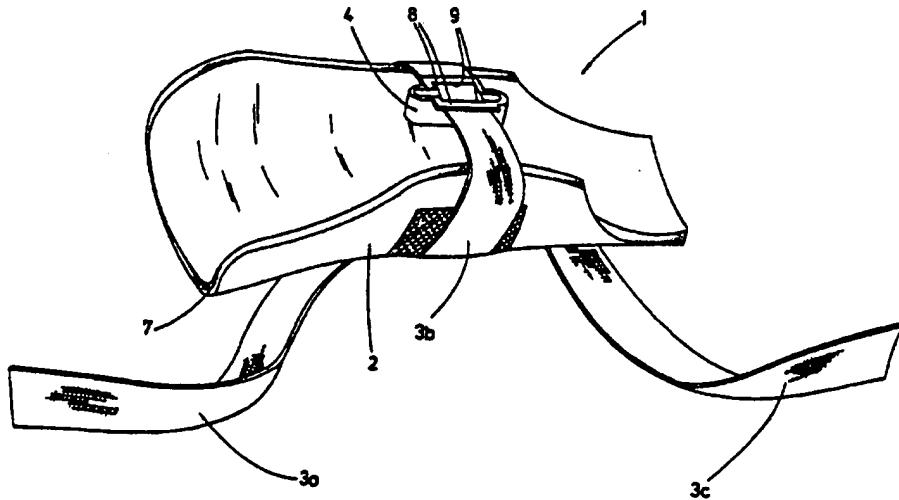




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<p>(21) International Application Number: PCT/SE96/00080</p> <p>(22) International Filing Date: 25 January 1996 (25.01.96)</p> <p>(30) Priority Data: 9500577-3 16 February 1995 (16.02.95) SE</p> <p>(71) Applicant (<i>for all designated States except US</i>): RADI MEDICAL SYSTEMS AB [SE/SE]; Palmbladsgatan 10, S-754 50 Uppsala (SE).</p> <p>(72) Inventors; and</p> <p>(73) Inventors/Applicants (<i>for US only</i>): ÅKERFELDT, Dan [SE/SE]; Nybla, S-755 92 Uppsala (SE). CHATELAIN, Pascal [CH/CH]; 65, chemin du Bois-Gourmand, CH-1255 Veyrier (CH).</p> <p>(74) Agents: LINDGREN, Anders et al.; Dr. Ludwig Brann Patentbyrå AB, P.O. Box 17192, S-104 62 Stockholm (SE).</p>		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AZ, BY, KG, KZ, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
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(54) Title: DEVICE FOR COMPRESSION OF AN ARTERY



(57) Abstract

The present invention relates to a device (1) for suppressing post-catheterization wound bleeding in the radial artery at the wrist (6) of a patient. The device comprises an elongated compression element (4), a pressure distribution and support plate (2) arranged essentially on the opposite side of the wrist (6) relative to said compression element (4), and one or more strap means (3a, 3b, 3c) for holding said compression element (4) and said pressure distribution plate (2) in place. The pressure distribution and support plate (2) have a bottom portion (11), a first side wall (10a) and a second side wall (10b). Said first side wall (10a) extends upwards a distance exceeding the thickness of the wrist. The plate (2) forms an angle, to enable the wrist (6) to be firmly maintained in a bent position. The pressure element (4) is slidably attached to one of the straps (3c), such that it may be positioned at various locations sideways across the wrist (6).

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Device for compression of an artery.

This invention relates to compression of artery in general, and in particular to a device for compression of the radial artery at the inner wrist after puncture.

Background of the Invention

There are numerous devices known for compression of artery at puncture sites for preventing and stopping bleeding, all of which are based on the principle of applying a very local pressure at the site of puncture. This is achieved by means of a small pad of some sort, the pad being held in place by a strap or the like, which is tightened around the limb, e.g arm or leg.

The main problem with the known devices and methods is that the devices when applied, hinder the flow of blood to and from the extremities, e.g. foot and hand, which may be experienced as painful to the patient, and could also have negative medical effects if the period of applying the pressure is extended, such as a few hours or more. Such extended time is often necessary in order to allow the tissue to heal sufficiently.

Furthermore, in most if not all known methods and devices, it is almost impossible to avoid that the patient moves his/her limbs to such an extent that bleeding will start again, and healing of the puncture will be rendered more difficult, unless the patient is confined to the bed.

US-4,182,338 (Stanulis) discloses an elastomeric appliance having a blunt abutting surface held in place over the wound by securing straps.

US-5,263,966 (Daneshvar) discloses a wrap which covers the groin area to support a specifically shaped pressure balloon.

EP-A1-0 554 602 (Sumitomo Rubber Ind. Ltd) discloses a compressive hemostatic belt comprising an inflatable balloon, mounted on a specific position of a strip of fiber cloth.

Another example of a device for applying pressure to a local point of the body is disclosed in UK-12,486 (Lalor).

All these prior art devices suffer from the mentioned drawback that the flow of blood will be substantially affected.

Summary of the Invention

The object of the invention is to provide a device of aforementioned type that overcomes the drawbacks of the prior art devices. In particular it is desired to shorten the time needed for hospitalization of patients after catheterization. It is also desired to provide simpler wound care after puncture of artery. Hematomas should also be prevented or eliminated if possible.

These objects are achieved by a device comprising a pressure distribution and support member or plate provided on the side opposite to the puncture site, whereby a local pressure applied to a compression element, placed over the puncture, will be distributed over a large surface on the opposite side. Thereby the pressure on the veins will not be high enough to block the return flow of blood from e.g. the hand.

In a preferred embodiment the pressure distribution plate is bent such that the hand is fixed in a bent position when the device is applied. Thereby access to the radial artery is made easier and also healing after puncture is facilitated.

The invention also provides a method of achieving local hemostasis of selected artery, e.g. the radial artery at the wrist, while maintaining blood flow through the surrounding artery and through the veins.

The compression device of the invention is defined in claim 1, and the method of the invention is defined in claim 9. Preferred embodiments are defined in the dependent claims.

Further scope of applicability of the present invention will become apparent from the detailed description given hereinafter. However, it should be understood that the detailed description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

Brief Description of the Drawings

The present invention will become more fully understood from the detailed description given hereinbelow and the accompanying drawings which are given by way of illustration only, and thus not limitative of the present invention, and wherein

Fig. 1 shows a perspective view of the device in detail;

Fig. 2 shows a cross section through a wrist with a device according to the invention applied thereto;

Fig. 3 is a perspective view of a device according to the invention applied to a patients wrist.

Description of Preferred Embodiments

In Fig. 1 there is shown a preferred embodiment of the device according to the invention, generally designated 1. It comprises a pressure distribution and support plate 2, a plurality of securing straps 3a-c, and a compression element 4, slidably connected to one of the straps 3c. The plate 2 is anatomically designed to fit exactly to the outer or top side 5 of the wrist

6. Especially there is provided a "dent" or "dimple" to accommodate the small "knuckle bone" at the wrist (caput ulnae). Furthermore the plate 2 is bent at the actual site of the wrist joint (shown with a B in the drawings), such that it enables the wrist to be supported by the pressure distribution plate and maintained fixed in a bent position. The pressure distribution plate is preferably made of a semi-rigid material such as polyethylene, but other materials are contemplated, e.g. metals such as aluminium. However, any material that is rigid enough to maintain the wrist and hand in a fixed, bent position will be adequate for the purpose of the invention. The rigid pressure distribution plate may be provided with a soft layer 7 of a foam material, such as polyurethane foam.

In the preferred embodiment shown in Fig. 1 the pressure distribution plate 2 is provided with three securing straps 3a, 3b, 3c, provided with coupling means for securing the device to the wrist and hand. The coupling means may be Velcro^R fastenings, or other suitable means, such as buckles or hooks or the like. The first strap 3a is provided on the distal part of the pressure distribution plate 2, for securing the fingers and palm of the hand in a backwardly bent position. The bending is advantageous i.a. in that it exposes the radial artery, thereby enabling puncture of the artery. The second strap 3b is provided at the proximal end of the pressure distribution plate 2 for securing the pressure distribution plate 2 to the lower part of the forearm. Finally there is a third strap 3c provided at the actual bend. On the third strap 3c there is provided a compression element 4. Said compression element is elongated and extends in the direction of the artery. It has preferably a slightly rounded contact surface in order to smoothly bear on the skin. The shown compression element 4 has two flanges 8 each having a slot 9 through which the strap 3c is passed, to provide a sliding attachment of said compression element 4 to said strap 3c. Thereby the element 4 may be adjusted to be positioned exactly where the radial artery is situated. The compression element 4 is preferably made of a soft plastic material such as EVA, but

pads made of other soft materials are also possible.

In a preferred embodiment the pressure distribution plate 2 exhibits a bending angle of approximately 30°. This angle may however be varied and is not critical to the function. The main reason for providing a bend is to facilitate penetration for catheterization purposes, since the artery will be better exposed when the wrist is bent.

Another preferred feature of the device is that at least one of the side walls or side supports 10a, 10b of the pressure distribution plate 2 extends upwards from the bottom portion 11 of the pressure distribution plate, such that there will be a space between the wrist 6 and at least the third strap 3c when the latter is tightened. Thus the compressive force induced by tightening the strap 3c will cause only the compression element 4 to bear against the wrist, i.e. the radial artery in the wrist, and thereby efficiently hinder the blood flow therein. At the same time the ulnar artery will still carry an undisturbed flow of blood, thereby supplying blood to the hand. Also the side support 10a remote from the radial artery will act as counter element to support the wrist under the pressure exerted by the compression element 4. The compression element will preferably have a major force component deviating from the perpendicular, as indicated with arrows in Fig. 2, such that the wrist will actually bear against said remote side wall 10a. Furthermore, the total compressive force exerted by tightening the straps will be efficiently distributed over the back side of the wrist and hand and the lower part of the forearm by the pressure distribution plate 2, such that venous blood flow will be practically undisturbed. Thereby one avoids any pain or other adverse medical effects caused by stoppage of blood flow to and from the hand. The second important effect of tightening the straps such that the hand is fixed in a bent position is that the patient will be prevented from flexing the wrist. Thereby the risk of disturbing the healing process at the puncture in an adverse way is greatly reduced, if not completely eliminated.

In another aspect the invention provides a method of achieving local hemostasis of selected artery, in a preferred embodiment the radial artery, while maintaining blood flow through surrounding artery and veins, in the preferred embodiment through the ulnar artery and through the veins in the hand and wrist. The method comprises applying a local pressure to a selected point or area on the selected (radial) artery at a limb (the wrist) of a patient, by means of a compression element. The applied pressure may be provided by straps wound around the limb (wrist) whereby the counterpressure is accommodated on the opposite side by a pressure distribution or support plate having a large surface area, such that the counterpressure is distributed over the entire surface of the back side of the limb (wrist).

The invention being thus described with reference to compression of the radial artery, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.

CLAIMS:

1. A device (1) for suppressing post-catheterization wound bleeding, comprising
 - a) a compression element (4) for application at the wound site;
 - b) a pressure distribution member (2) arranged essentially on the opposite side relative to said pressure element (4);
 - c) securing means (3a, 3b, 3c) for holding said pressure element (4) and said pressure distribution member (2) in place on opposite sides of the wrist (6), and for generating a sufficient pressure to stop blood flow only at said wound site, while at the same time allowing blood flow in surrounding arteries and veins.
2. The device as claimed in claim 1, wherein said pressure distribution member (2) is bent in the vicinity (B) of the wrist joint.
3. The device as claimed in claim 2, wherein said member (2) is bent at an angle of 15 - 60°, preferably 30 - 50°, in said vicinity of said wrist joint.
4. The device as claimed in any preceding claim, wherein said compression element (4) is elongated in the direction of an artery to which it is applied.

5. The device as claimed in any of the preceding claims, wherein said securing means comprises a plurality of straps (3a, 3b, 3c) attached to said pressure distribution member (2) for holding said compression element (4) and said pressure distribution member (2) in place when tightened around a body portion (6) where bleeding is to be stopped.

6. The device as claimed in claim 5, wherein said compression element (4) is slidably attached to one of said straps (3c).

7. The device as claimed in any of the preceding claims, wherein said pressure distribution member (2) comprises a bottom portion (11) and two side walls (10a, 10b), and wherein at least one of said side walls (10a) extends upwards from the bottom portion (11) of the pressure distribution member (2), such that there will be a space between said body portion (6) and at least one of the stradps (3c) when the latter is tightened.

8. The device as claimed in any of the preceding claims, wherein the wound is a punction in the radial artery, and said body portion is the wrist (6) of a patient.

9. A method of achieving local hemostasis of selected artery while maintaining blood flow through surrounding artery and veins, by providing a compression element at a selected point of said selected artery at a limb of a patient, and a pressure distribution member having a large surface on the opposite side, and applying a tightening means around the compression element and pressure distribution member to provide a pressure, whereby the counterpressure is distributed over the entire surface of the back side of said limb.

10. The method as claimed in claim 9, wherein said artery is the radial artery and said limb is the wrist.

11. A device (1) for suppr ssing post-catheterization wound bleeding in the radial artery at the wrist (6) of a patient,

comprising

a) an elongated compression element (4) for application against the radial artery at the wound site;

b) a pressure distribution and support member (2) arranged essentially on the opposite side of the wrist (6) relative to said compression element (4), said pressure distribution and support member (2) having a bottom portion (11), a first side wall (10a) and a second side wall (10b), said first side wall (10a) extending upwards a distance exceeding the thickness of the wrist; said bottom portion (11) comprising a first, proximal portion resting along the wrist (6), and a second, distal portion forming an angle with said first proximal portion, to enable the wrist (6) to be firmly maintained in a bent position, and

c) one or more strap means (3a, 3b, 3c) for holding said compression element (4) and said pressure distribution member (2) in place on opposite sides of the wrist (6);

said pressure element (4) being slidably attached to one of the straps (3c), such that it may be positioned at various locations sideways across the wrist (6).

1/3

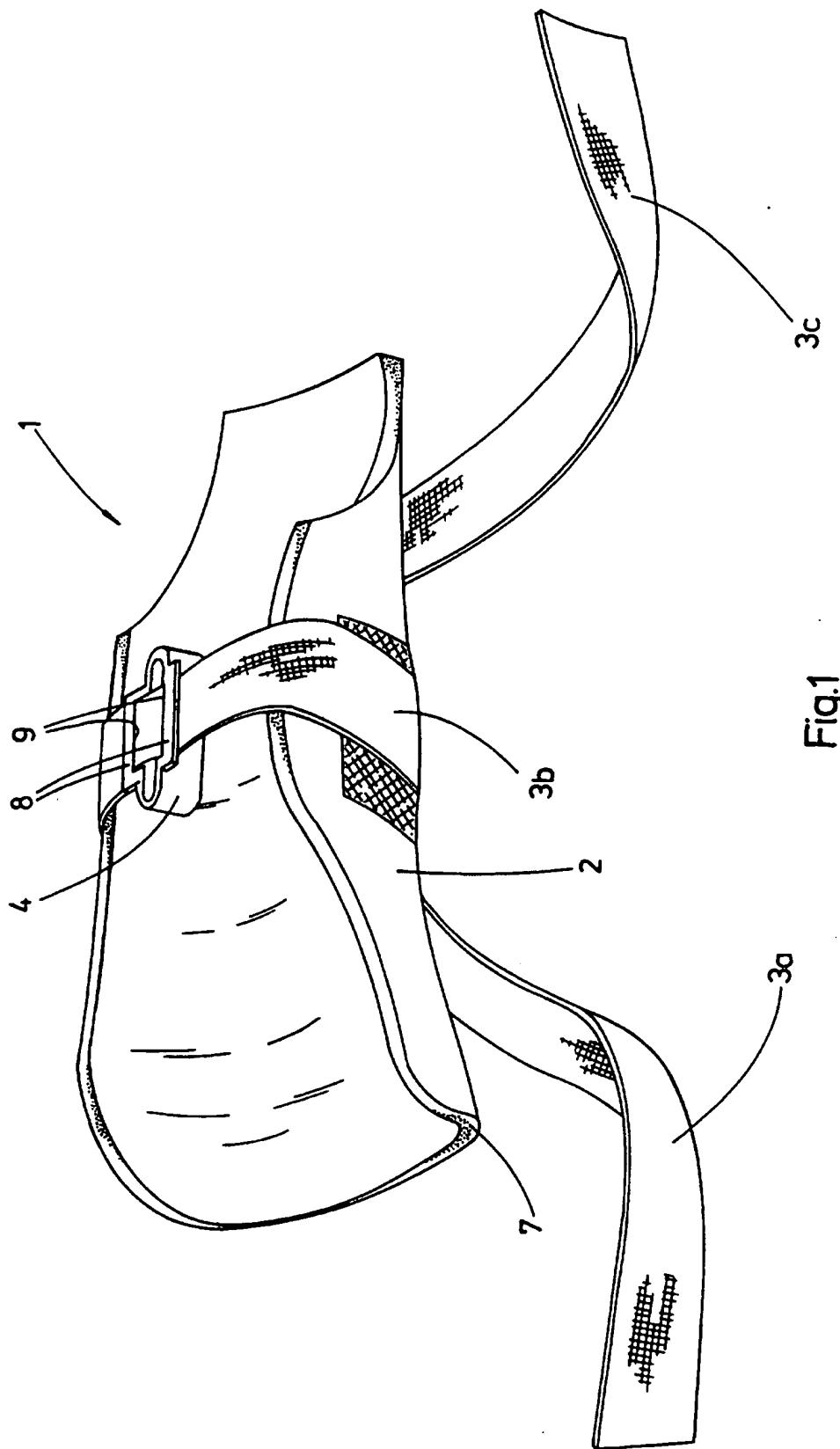


Fig.1

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2/3

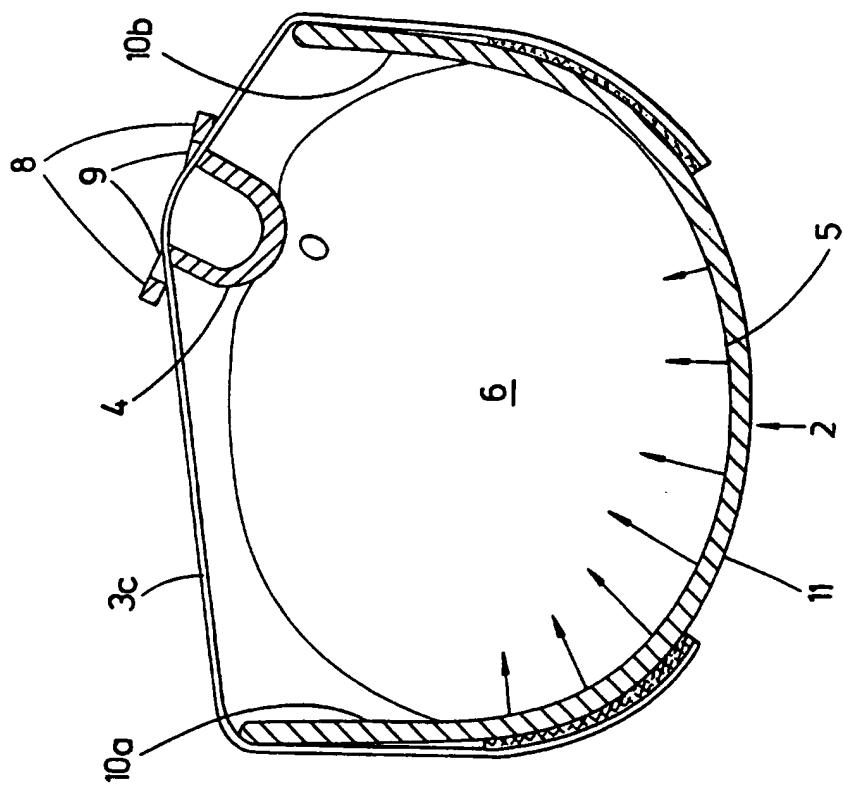
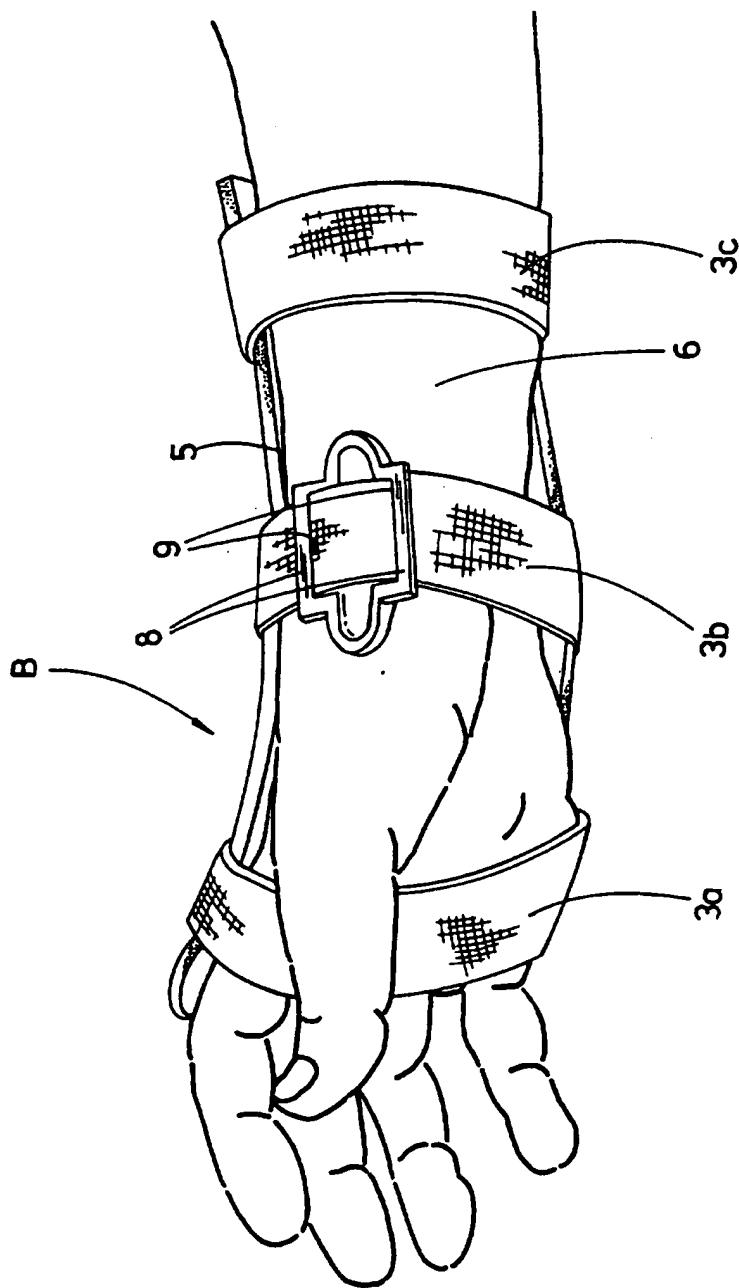


Fig.2

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3/3

Fig.3



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 96/00080

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5304201 A (RICE), 19 April 1994 (19.04.94), column 3, line 6 - line 58; column 6, line 24 - line 48, figures 1,3	1,4-6,8-11
Y	--	2-3,7
Y	US 4798199 A (HUBBARD ET AL), 17 January 1989 (17.01.89), column 3, line 20 - line 66, figures 1, 10	2-3,7
A	-- US 3954109 A (PATEL), 4 May 1976 (04.05.76), column 1, line 5 - line 26, figure 4 -- -----	1-11

<input type="checkbox"/>	Further documents are listed in the continuation of Box C.	<input checked="" type="checkbox"/> See patent family annex.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

01/04/96

International application No.

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 5304201	19/04/94	NONE	
US-A- 4798199	17/01/89	NONE	
US-A- 3954109	04/05/76	NONE	